

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>Proprietary Laboratory Analyses (PLA) codes represent proprietary laboratory services. The following codes may include a range of laboratory tests including, but not limited to multianalyte assays with algorithmic analyses (MAAA) and genomic sequencing procedures (GSP). MAAAs are procedures that utilize multiple results derived from assays of various types, including molecular pathology assays, fluorescent in situ hybridization assays and non-nucleic acid-based assays (for example, proteins, polypeptides, lipids, carbohydrates). Consistent with CPT® coding guidelines, when a PLA code is available, the specific PLA code takes precedence.</p>				
<p>0017M Oncology (diffuse large b-cell lymphoma [dlbcl]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin embedded tissue, algorithm reported as cell of origin</p>	No	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C83.30, C83.31, C83.32, C83.33, C83.34, C83.35, C83.36, C83.37, C83.38, C83.39</p>	Once in a lifetime, except with valid TAR override	
<p>0001U Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported</p>	No	Ordered by hematologist/oncologist	N/A	
<p>0003U Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score</p>	No	<p>The following ICD-10-CM diagnosis code is required on the claim: R19.09</p> <p>Reimbursable for females who meet the following criteria:</p> <ul style="list-style-type: none"> • 18 years of age or older and • Ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist 	Once in a lifetime, except with valid TAR override	

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		<p>(temporal, parietal occipital) either on diffusion-weighted imaging (DWI) or fluid attenuated inversion recovery (FLAIR)</p> <p>3. And routine investigations do not indicate an alternative diagnosis</p>		
<p>0037U Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden.</p>	As Noted	<p>A TAR is not required when the following criteria are met:</p> <ul style="list-style-type: none"> • The patient has either recurrent, relapsed, refractory, metastatic or advanced stages III or IV cancer, and • The patient either has not been previously tested using the same Next Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician, and • The decision for additional cancer treatment is contingent on the test results. <p>A TAR is required for all other cancer diagnosis that are not advanced. Required Documentation: diagnosis and stage of malignancy and the chart notes, must show the medical necessity for this test for therapeutic decisions.</p>	N/A	<p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p>
<p>0040U BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative</p>	No	<p>The following ICD-10-CM diagnosis code is required on the claim: C92.10.</p>	Once per year, except with valid TAR override	

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		<p>mutations) or</p> <p>e. Unfavorable intermediate-risk when considering decisions to proceed with treatment (i.e. add androgen deprivation therapy to radiation).</p> <p>2. Result of the test, when considered as a whole with routine clinical factors, is likely to influence the decision to proceed with surveillance or treatment.</p> <p>For post-prostatectomy patients who seek guidance on adjuvant vs. salvage radiation:</p> <p>1. Coverage is limited to Decipher Genomic Classifier</p> <p>2. Result of the test, when considered as a whole without routine clinical factors, is likely to affect treatment</p>		
<p>0049U NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, quantitative</p>	<p>No</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C92.00 thru C92.02, C92.60 thru C92.62, C92.A0 thru C92.A2</p>	<p>Once per year</p>	
<p>0050U Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements</p>	<p>No</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C92.00 thru C92.02, C92.60 thru C92.62, C92.A0 thru C92.A2</p>	<p>Once per year</p>	
<p>0058U Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel</p>	<p>No</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C4A.0, C4A.10 thru C4A.12, C4A.20 thru C4A.22, C4A.30 thru</p>	<p>Once-in-a-lifetime, except</p>	

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cell polyoma virus oncoprotein (small T antigen), serum, quantitative		C4A.39, C4A.51 thru C4A.59, C4A.60 thru C4A.62, C4A.70 thru C4A.72, C4A.8, C4A.9	with valid TAR override	
0059U Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C4A.0, C4A.10 thru C4A.12, C4A.20 thru C4A.22, C4A.30 thru C4A.39, C4A.51 thru C4A.59, C4A.60 thru C4A.62, C4A.70 thru C4A.72, C4A.8, C4A.9	Once-in-a-lifetime, except with valid TAR override	
0081U Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C69.30 thru C69.32, C69.40 thru C69.42 Repeat testing requires chart notes that show results will direct treatment	Once per year, except with valid TAR override	
0084U Red blood cell antigen typing, DNA, genotyping of 10 blood groups with phenotype prediction of 37 red blood cell antigens	No	Hematology must order	N/A	
0087U Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score	No	The following ICD-10-CM diagnosis code is required on the claim: Z94.1	Once per year	
0088U Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue,	No	The following ICD-10-CM diagnosis code is required on the claim: Z94.0	Once per year	

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algorithm reported as a probability score for rejection				
0118U Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell free DNA in the total cell-free DNA	Yes	A TAR requires documentation of the following criteria: For kidney transplant recipients <ul style="list-style-type: none"> • There is clinical suspicion for acute kidney allograft rejection and the member has not been tested with another donor-derived cell-free DNA test for the same episode, and • The test must be ordered by a nephrologist or kidney transplant surgeon, and • Member is at least one month post-kidney transplant, and • Member is 18 years of age or older, and • Member is not pregnant, and • Member has not received a kidney transplant from their twin, has not undergone multiple organ transplants, and has not undergone bone marrow transplantation 	N/A	Partnership would consider for heart, lung and liver transplant with MD review for medical necessity.
0120U Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C83.30 thru C83.39, C85.20 thru C85.29	Once per year	

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<p>0154U Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3)</p>	No	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C67.0 thru C67.9</p>	Once-in-a-lifetime, except with valid TAR override	
<p>0155U Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (e.g., breast cancer) gene analysis (i.e., p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y)</p>	No	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C50.011 thru C50.929</p>	Once-in-a-lifetime, except with valid TAR override	
<p>0157U APC (APC regulator of WNT signaling pathway) (e.g., familial adenomatous polyposis [FAP]) mRNA sequence analysis (List separately in addition to code for primary procedure)</p>	No	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C18.0 thru C18.9, D12.0 thru D12.9, K63.5, Z86.010</p>	Once-in-a-lifetime, except with valid TAR override	
<p>0158U MLH1 (mutL homolog 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)</p>	No	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42</p>	Once-in-a-lifetime, except with valid TAR override	

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0159U MSH2 (mutS homolog 2) (e.g., hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, except with valid TAR override	
0160U MSH6 (mutS homolog 6) (e.g., hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, except with valid TAR override	
0161U PMS2 (PMS1 homolog 2, mismatch repair system component) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, except with valid TAR override	
0162U Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure)	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, except with valid TAR override	
0165U Peanut allergen-specific quantitative assessment of epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy.	No	One of the following ICD-10-CM diagnosis codes is required on the claim: Z01.82, Z91.010 Repeat testing requires chart notes that show results will direct treatment.	Once per year except with valid TAR override with clinical justification	

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0169U NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (e.g., drug metabolism) gene analysis, common variants	Yes	The service requires a TAR with documentation of the following criteria: <ul style="list-style-type: none"> • That the patient is undergoing thiopurine therapy, and • The patient has severe or prolonged myelosuppression. 	Once-in-a-lifetime, except with valid TAR override	
0171U Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C92.00, C92.01, C92.02, C92.10 thru C92.22, C95.10, D45, D46.0, D46.1, D46.20 thru D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z, D47.1, D47.3.	Once per year	
0172U Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	Yes	The service requires a TAR with documentation of the following criteria: <ol style="list-style-type: none"> 1. The patient has advanced ovarian, fallopian tube or primary peritoneal cancer and 2. Treatment is contingent on the result of the test 	Once-in-a-lifetime, except with valid TAR override	
0177U Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status	Yes	The service requires a TAR with documentation of the following criteria: <ol style="list-style-type: none"> 1. The patient has confirmed diagnosis of breast cancer and 2. Treatment is contingent the result of the test 	Once-in-a-lifetime, except with valid TAR override	

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0178U Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction.	No	DX code Z91.01, CPT 95180 Ordered by Allergist TAR override if >50 /day above ICD-10 codes with clinical notes showing the medical necessity	50/day, except with valid TAR override	
0180U Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/ conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyl-transferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons	No	Ordered by hematologist	Once per year	
0181U Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1	No	Ordered by hematologist	Once per year	
0182U Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10	No	Ordered by hematologist	Once per year	
0183U Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19	No	Ordered by hematologist	Once per year	

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0184U Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2	No	Ordered by hematologist	Once per year	
0185U Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4	No	Ordered by hematologist	Once per year	
0186U Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2	No	Ordered by hematologist	Once per year	
0187U Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2	No	Ordered by hematologist	Once per year	
0188U Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4	No	Ordered by hematologist	Once per year	
0189U Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2	No	Ordered by hematologist	Once per year	

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0190U Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3	No	Ordered by hematologist	Once per year	
0191U Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6	No	Ordered by hematologist	Once per year	
0192U Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9	No	Ordered by hematologist	Once per year	
0193U Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26	No	Ordered by hematologist	Once per year	
0194U Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8	No	Ordered by hematologist	Once per year	
0195U KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)	No	Ordered by hematologist	Once per year	

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0196U Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3	No	Ordered by hematologist	Once per year	
0197U Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1	No	Ordered by hematologist	Once per year	
0198U Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5	No	Ordered by hematologist	Once per year	
0199U Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12	No	Ordered by hematologist	Once per year	
0200U Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3	No	Ordered by hematologist	Once per year	

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0216U Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants	No	One of the following ICD-10-CM diagnosis codes is required on the claim: G11.0, G11.3, G11.9, G11.10, G11.11, G11.19, R26.0, R27.0.	Once per year except with valid TAR override	
0217U Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants	No	One of the following ICD-10-CM diagnosis codes is required on the claim: G11.0, G11.3, G11.9, G11.10, G11.11, G11.19 R26.0, R27.0.	Once per year, except with valid TAR override	
0218U Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants	Yes	The service requires a TAR with documentation of the following criteria: <ul style="list-style-type: none"> • Patient has a clinical diagnosis of dystrophinopathy based on the history, physical examination and elevated creatinine kinase (CK) level and • Result of the DMD (dystrophin) deletion or duplication is negative 	N/A	
0219U Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm	No	One of the following ICD-10-CM diagnosis codes is required on the claim: B20, Z21. TAR override with above ICD 10 and Clinical notes showing medical necessity for repeat testing	Once per year, except with valid TAR override	

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reported as prediction of antiviral drug susceptibility				
0221U Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene	No	Ordered by hematologist	Once per year	
0222U Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3	No	Ordered by hematologist	Once per year	
0230U AR (androgen receptor) (e.g., spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	Yes	The service requires a TAR with documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for bulbar muscular atrophy, and • The patient requires the service as a confirmatory test for spinal and bulbar muscular atrophy 	Once in a lifetime	
0231U CACNA1A (calcium voltage-gated channel subunit alpha 1A) (e.g., spinocerebellar ataxia), full gene analysis, including small sequence	Yes	The service requires a TAR with documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for Episodic 	N/A	

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<p>changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions</p>		<p>ataxia type 2 (EA2), and</p> <ul style="list-style-type: none"> The patient requires the service as a confirmatory test for EA2 		
<p>0232U CSTB (cystatin B) (e.g., progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions</p>	Yes	<p>The service requires a TAR with documentation of the following criteria:</p> <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for myoclonic epilepsy type 1 and requires the service as a confirmatory test for myoclonic epilepsy type 1, and Treatment will be contingent on test results 	Once in a lifetime	
<p>0233U FXN (frataxin) (e.g., Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions</p>	Yes	<p>The service requires a TAR with documentation of the following criteria:</p> <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for Friedreich ataxia (FRDA), and The patient requires the service as a confirmatory test for FRDA 	Once in a lifetime	
<p>0234U MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element</p>	Yes	<p>The service requires a TAR with documentation of the following criteria:</p> <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for Rett syndrome, and 	Once in a lifetime	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>insertions, and variants in non-uniquely mappable regions</p>		<ul style="list-style-type: none"> The patient requires the service as a confirmatory test for Rett syndrome 		
<p>0235U PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions <i>(continues)</i></p> <p><i>(continued from above)</i></p>	<p>Yes</p>	<p>The service requires a TAR with documentation of the following criteria:</p> <ol style="list-style-type: none"> Individual with a personal history of: <ol style="list-style-type: none"> Bannayan-Riley-Ruvalcaba syndrome, or Adult Lhermitte-Duclos disease, or Autism spectrum disorder AND macrocephaly, or Two or more biopsy-proven trichilemmomas, or Two or more major criteria (one macrocephaly), or Three major criteria without macrocephaly, or One major and three or more minor criteria, or Four or more minor criteria (please see list of major and minor criteria below) At-risk individual <ol style="list-style-type: none"> With a relative who has a clinical diagnosis of Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome for whom testing has not been performed AND who has any one major criterion or two minor criteria 	<p>N/A</p>	
<p>0235U PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions</p>	<p>Yes</p>	<p><u>Clinical Criteria:</u> Major Criteria</p> <ul style="list-style-type: none"> Breast Cancer Mucocutaneous lesions One biopsy-proven trichilemmoma Multiple palmoplantar keratosis Multifocal or extensive oral mucosal papillomatosis Multiple cutaneous facial papules (often verrucous) 	<p>N/A</p>	

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
		<ul style="list-style-type: none"> • Macular pigmentation of glans penis • Macrocephaly (megalencephaly, ie, $\geq 97^{\text{th}}$ percentile) • Endometrial cancer • Non-medullary thyroid cancer • Multiple GI tract hamartomas or ganglioneuromas <p>Minor Criteria</p> <ul style="list-style-type: none"> • Other thyroid lesions (adenoma, nodule, goiter) • Mental retardation (IQ ≤ 75) • Autism spectrum disorder • Single GI tract hamartoma or ganglioneuroma • Fibrocystic disease of the breast • Lipomas • Fibromas • Renal cell carcinoma • Uterine fibroids 		
<p>0236U SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (e.g., spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions</p>	Yes	<p>The service requires a TAR.</p> <p>One of the following ICD-10-CM diagnosis codes is required on the claim: O09.00 thru O09.93, Z31.430, Z31.440, Z34.00 thru Z34.03, Z34.80 thru Z34.83, JZ34.90 thru Z34.93.</p>	Once in a lifetime, except with valid TAR override	
<p>0237U Cardiac ion channelopathies (e.g., Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia),</p>	Yes	<p>The service requires a TAR.</p> <p>The TAR must document a copy of the report of the physician interpreted 12-lead electrocardiogram (ECG) with pattern consistent with or suspicious for prolonged QT</p>	Once in a lifetime, except with valid TAR override	

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions		interval. The TAR must also have clinical documentation of one or more of the following: <ol style="list-style-type: none"> 1. Torsade de pointes in the absence of drugs known to prolong QT interval 2. T-wave alternans 3. Notched T-wave in three leads 4. Syncope 5. Family members with long QT syndrome 6. Sudden death in family members less than 30 years of age without defined cause 		
0238U Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once in a lifetime	
0239U Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations	Yes	The service requires a TAR. A TAR requires documentation of the following criteria: <ol style="list-style-type: none"> 1. The patient has a diagnosis of either: <ul style="list-style-type: none"> - Non-small cell lung cancer (plasma), or - Metastatic castrate resistant prostate cancer 2. And treatment is contingent on the test result. 	N/A	
0242U Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence	Yes	The service requires a TAR with documentation of the following criteria: <ul style="list-style-type: none"> • Patient has diagnosis of either <ul style="list-style-type: none"> - Non-small cell lung cancer, or - Hormone receptor-positive, Human 	Once in a lifetime	

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
with phenotype prediction of at least 51 red blood cell antigens				
0268U Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid	Yes	The service requires a TAR with documentation of the following criteria: 1. The patient has clinical signs of symptoms for atypical hemolytic uremic syndrome (aHUS), and 2. The patient requires the service as a diagnostic test for aHUS	Once in a lifetime	
0269U Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid	Yes	The service requires a TAR A TAR requires documentation of the following criteria: 1. The patient has clinical signs of symptoms suspicious for autosomal dominant congenita thrombocytopenia, and 2. The patient requires the service as a diagnostic test for autosomal dominant congenital thrombocytopenia	Once in a lifetime	
0271U Hematology (congenital neutropenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	No	One of the following ICD-10-CM diagnosis codes is required on the claim: D70.0, D70.1, D70.2, D70.3, D70.4, D70.8, and D70.9. TAR over-ride allowed for ICD-10 codes	Once in a lifetime, except with valid TAR override	
0276U Genomic sequence analysis of 42 genes for detection of abnormalities associated with inherited thrombocytopenia (low platelet count)	Yes	The service requires a TAR A TAR requires documentation of the following criteria: 1. The patient has clinical signs or symptoms suspicious for inherited thrombocytopenia, and 2. The patient requires the service as a	Once in a lifetime	

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
		diagnostic test for inherited thrombocytopenia		
0282U Red blood cell antigen typing, dna, genotyping of 12 blood group system genes to predict 44 red blood cell antigen phenotypes	No	Ordered by hematologist	Once per year	
0286U CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	Yes	The service requires a TAR A TAR requires documentation of the following criteria: <ul style="list-style-type: none"> • That the patient is undergoing thiopurine therapy, and • The patient has severe or prolonged myelosuppression 	N/A	
0287U Oncology (thyroid), DNA and mRNA, next-generation sequencing analysis of 112 genes, fine needle aspirate or formalin-fixed paraffin-embedded (FFPE) tissue, algorithmic prediction of cancer recurrence, reported as a categorical risk result (low, intermediate, high)	Yes	The service requires a TAR. A TAR requires documentation of the following criteria: <ol style="list-style-type: none"> 1. The patient is under evaluation for thyroid nodule(s), and 2. The cytopathology result from fine needle aspiration is indeterminate, defined as one of the following: <ol style="list-style-type: none"> a. Follicular lesion of undetermined significance (FLUS), Bethesda III, or b. Atypia of undetermined significance (AUS), Bethesda III, or c. Follicular neoplasm, Bethesda IV. 3. And the diagnostic or treatment strategy will be contingent on test results 	Once in a lifetime, except with valid TAR override	
0314U Oncology (cutaneous melanoma),	Yes		One unit per day,	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)</p>		<p>Ordered by Dermatology or Oncologist ICD-10 C43 and clinical notes showing medical necessity for repeat testing</p>	<p>except with valid TAR override</p>	
<p>0326U Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden</p>	<p>Yes</p>	<p>A TAR is required for malignancy diagnosis. Clinical information must be submitted showing diagnosis, staging and medical necessity where the treatment is directed by the results.</p>	<p>Once after recurrence, MORE frequently if there is a recurrence or progression with TAR override for medical necessity where treatment is directed by results</p>	<p>NCCN guideline recommendations will be reviewed for medical necessity</p> <p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p>
<p>0327U Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma,</p>	<p>Yes</p>	<p>A TAR is required with clinical information indicating pregnancy and not previously tested in this pregnancy.</p>	<p>Once per pregnancy, consider repeat with TAR</p>	<p>Reimbursement will be limited to one of the following Noninvasive Prenatal Tests per</p>

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>algorithm reported as a risk score for each trisomy, includes sex reporting, if performed</p>			<p>override for medical necessity showing indication for repeat testing and treatment is directed by results</p>	<p>pregnancy: PLA code 0327U or CPT code 81420 or CPT code 81507. Concurrent or repeat use of these services during the same pregnancy is not covered unless there is documentation of medical necessity.</p>
<p>0329U Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations</p>	<p>Yes</p>	<p>A TAR is required with documentation of the following criteria: <u>For Somatic Testing</u></p> <ul style="list-style-type: none"> • The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and • The patient either has not been previously tested using the same Next-Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and <p>The decision for additional cancer treatment is contingent on the test results.</p>	<p>Once per year and /or after recurrence or progression with TAR override for medical necessity where treatment is directed by results</p>	<p>NCCN guideline recommendations will be reviewed for medical necessity As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p>

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>0333U Oncology (liver), surveillance for hepatocellular carcinoma (hcc) in highrisk patients, analysis of methylation patterns on circulating cell-free dna (cfdna) plus measurement of serum of afp/afp-l3 and oncoprotein des-gammacarboxy-prothrombin (dcp), algorithm reported as normal or abnormal result</p>	Yes	<p>TAR Required with Dx of High risk for hepatocellular carcinoma, notation that standard surveillance AFP and imagining is insufficient or inconclusive and subsequent treatment options contingent on results</p>	Once in a lifetime	<p>Of note this testing is NOT supported in the 2023 NCCN guidelines</p>
<p>0334U Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin embedded (ffpe) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden</p>	Yes	<p>A TAR is required with documentation of the following criteria: <u>For Somatic Testing</u></p> <ul style="list-style-type: none"> • The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and • The patient either has not been previously tested using the same Next-Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and • The decision for additional cancer treatment is contingent on the test results. 	Once in a lifetime	<p>NCCN guideline recommendations will be reviewed for medical necessity</p> <p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or</p>

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
				metastatic stage 3 or 4 cancer.
0339U Oncology (prostate), mrna expression profiling of hoxc6 and dlx1, reverse transcription polymerase chain reaction (rt-pcr), first-void urine following digital rectal examination, algorithm reported as probability of high-grade cancer	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C61, D07.5. Allow TAR/SAR override.	Once in 36 months, except with valid TAR override	
0340U Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease burden correlation, if appropriate	Yes	NCCN guideline recommendations will be reviewed. A TAR requires documentation of all of the following criteria (1 thru 3): 1. The member is not receiving other molecular testing for minimal residual disease analysis concurrently with this test, and 2. One of the following criteria must be met (a or b), and: a. Monitoring is needed to diagnose cancer recurrence, relapse or progression and member has a diagnosis of one of the following: muscle-invasive bladder cancer, stage II to IV ovarian cancer, stage II to IV breast cancer, non-small cell lung cancer, Merkel cell carcinoma, or stage II to IV colorectal cancer, or b. Monitoring of response is needed and member is receiving immune checkpoint inhibitor therapy for a diagnosis of any solid tumor	Based on NCCN guidelines	

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>0340U cont'd Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease burden correlation, if appropriate</p>		<p>3. One of the following criteria must be met (a thru d):</p> <ul style="list-style-type: none"> a. Member is currently being treated for cancer and the test has not been previously performed for this cancer diagnosis, or b. Member is currently being treated for cancer and there is clinical suspicion that the molecular profile of the member's tumor has changed, or c. Member is not currently being treated for their cancer (i.e. when there is no clinical, radiographical or other biological evidence that tumor cells remain post treatment and the member is no longer being subjected to therapeutic interventions for cancer) and the test has not been performed in the last 12 months, or d. Member is not currently being treated for their cancer and now there is a clinical suspicion for tumor recurrence 		
<p>0341U Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid</p>	Yes	<p>TAR required with Prenatal Care diagnosis and clinical information showing medical necessity including explanation of why the covered code 0327U cannot be used</p>	Once per pregnancy	
<p>0345U Psychiatry (e.g., depression, anxiety, attention deficit hyperactivity disorder</p>	Yes	<p>A TAR requires documentation of all of the following criteria:</p> <ul style="list-style-type: none"> • Member is 18 years of age or older, and 	Once in a lifetime	Consider for evaluation of a Member's genetic predisposition to a CYP450

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>[ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6</p> <p>0345U Psychiatry (e.g., depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6</p>		<ul style="list-style-type: none"> • Diagnosis of major depressive disorder of at least moderate severity, and • Non-pharmacologic treatment has been tried and failed or member’s condition is not appropriate for non-pharmacological treatment, and • Prior inadequate response and/or significant adverse reaction to at least two psychotropic drugs must be documented in the medical record, and • Psychotropic drug(s) being considered for treatment has a known and clinically actionable gene-drug interaction based on one of the following: <ul style="list-style-type: none"> – Clinical Pharmacogenetics Implementation Consortium (CPIC) final Level A or B https://cpicpgx.org/genes-drugs/ or, – The U.S. Food and Drug Administration (FDA) Section 1 Table “Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, or – The current FDA-approved prescribing label for the drug. 	<p>No TAR override allowed</p>	<p>enzyme interaction, which may pose a risk for adverse drug reaction.</p> <p>Clinical Pharmacogenetics Implementation Consortium Guideline from the FDA can be found here: https://cpicpgx.org/genes-drugs/</p>
<p>0359U Oncology (prostate cancer), analysis of all prostate-specific antigen (PSA) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer</p>	<p>No</p>	<p>Reimbursable for males who meet the following criteria:</p> <ul style="list-style-type: none"> • 40 years of age or older • One of the following ICD-10-CM diagnosis codes is required on the claim: N40.0, N40.1, N40.2, N40.3, Z12.5, Z80.42 	<p>Twice per year, except with valid TAR override</p>	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
0364U Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (pcr) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (mrd) with quantitation of disease burden, when appropriate	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C90.00, C90.01, C90.02, C91.00, C91.01, C91.02, C91.10, C91.11, C91.12.	N/A Allow TAR override	
0371U Infectious agent detection by nucleic acid (dna or rna), genitourinary pathogen, semiquantitative identification, dna from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qpcr), urine	Yes	TAR required with diagnosis of Urinary Tract infection and documentation showing that testing is required to direct treatment	N/A	
0372U Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score	Yes	Documentation of genitourinary tract infection and risk for antibiotic resistance ICD 10 Z16, Z16.24	N/A	
0373U Infectious agent detection by nucleic acid (dna and rna), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen	Yes	Documentation of respiratory tract infection and risk for antibiotic resistance ICD 10 Z16, Z16.24	Two times per year, except with valid TAR override	
0374U Infectious agent detection by nucleic acid (dna or rna), genitourinary pathogens, identification of 21 bacterial and fungal	Yes	Documentation of genitourinary tract infection and risk for antibiotic resistance	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine</p>				
<p>0378U Rfc1 (replication factor c subunit 1), repeat expansion variant analysis by traditional and repeat-primed pcr, blood, saliva, or buccal swab</p>	No	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: G11.0, G11.2, G11.3, G11.4, G11.8, G11.9, G11.10, G11.11, G11.19, G32.81, G60.2, G80.4, R26.0, R27.0.</p>	Once in a lifetime, except with valid TAR override	
<p>0379U Targeted genomic sequence analysis panel, solid organ neoplasm, dna (523 genes) and rna (55 genes) by next-generation sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden</p>	Yes	<p>A TAR is required with documentation of the following criteria: <u>For Somatic Testing</u></p> <ul style="list-style-type: none"> • The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and • The patient either has not been previously tested using the same Next-Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and <p>The decision for additional cancer treatment is contingent on the test results.</p>	Once in a lifetime, except with valid TAR override	<p>NCCN guideline recommendations will be reviewed for medical necessity</p> <p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p>

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
0381U Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement of allo-isoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry (lc-ms/ms)	No	One of the following ICD-10-CM diagnosis codes is required on the claim: E71.0, E71.2	Allow TAR override for tests of more than 20 per year with documentation demonstrating medical need for more frequent testing	
0382U Hyperphenylalaninemia monitoring by patient-collected blood card sample, quantitative measurement of phenylalanine and tyrosine, liquid chromatography with tandem mass spectrometry (lc-ms/ms)	No	One of the following ICD-10-CM diagnosis codes is required on the claim: E70.0 and E70.1	N/A Allow TAR override	
0383U Tyrosinemia type i monitoring by patient-collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography with tandem mass spectrometry (lc-ms/ms)	No	One of the following ICD-10-CM diagnosis codes is required on the claim: E70.20, E70.21, E70.29	N/A Allow TAR override	
0388U Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection	Yes	TAR requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has a diagnosis of non-small cell lung cancer • The patient is medically unable to undergo invasive biopsy or tumor tissue testing is not feasible • Management is contingent on the test results 	Once in a lifetime, except with valid TAR override	

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>0391U Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splice-site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score</p>	<p>Yes</p>	<p>A TAR is required with documentation of the following criteria: <u>For Somatic Testing</u></p> <ul style="list-style-type: none"> • The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and • The patient either has not been previously tested using the same Next-Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and • The decision for additional cancer treatment is contingent on the test results. 	<p>Once in a lifetime, except with valid TAR override</p>	<p>NCCN guideline recommendations will be reviewed for medical necessity. As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p>
<p>0409U Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability</p>	<p>Yes</p>	<p>A TAR is required with documentation of the following criteria:</p> <ul style="list-style-type: none"> • The patient has a diagnosis of non-small cell lung cancer, and • The patient is medically unable to undergo invasive biopsy or tumor tissue testing is not feasible, and • Management is contingent on the test results 	<p>Once in a lifetime except with valid TAR override</p>	

MCUP3131-C Proprietary Lab Analyses Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full code descriptions.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
0471U Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalin-fixed paraffin-embedded (FFPE), predictive, identification of detected mutations	Yes	A TAR is required with documentation of the following criteria: <ul style="list-style-type: none"> The patient has been diagnosed with colorectal cancer, and Management is contingent on the test results 	Once in a lifetime except with valid TAR override	
0473U Oncology (solid tumor), next-generation sequencing (NGS) of DNA from formalin-fixed paraffin-embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden	Yes	A TAR is required with documentation of the following criteria: <p><u>For Somatic Testing</u></p> <ul style="list-style-type: none"> The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and The patient either has not been previously tested using the same Next-Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and The decision for additional cancer treatment is contingent on the test results. <p>Independent of the above criteria, somatic testing may be approved if the test is approved by the U.S. Food and Drug Administration (FDA) as a companion diagnostic device, and the decision for additional treatment is contingent on the test results.</p>	Once in a lifetime except with valid TAR override	NCCN guideline recommendations will be reviewed for medical necessity. As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.
0475U Hereditary prostate cancer-related disorders, genomic sequence analysis	Yes	A TAR requires documentation of the following criteria: <p><u>For Germline Testing</u></p>	Once in a lifetime	

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<p>panel using next-generation sequencing (NGS), Sanger sequencing, multiplex ligation-dependent probe amplification (MLPA), and array comparative genomic hybridization (CGH), evaluation of 23 genes and duplications/deletions when indicated, pathologic mutations reported with a genetic risk score for prostate cancer</p>		<ul style="list-style-type: none"> • The patient has prostate cancer, and • The patient has a clinical indication for germline (inherited) testing for hereditary cancer (e.g., NCCN Guidelines for Prostate Cancer), and • The patient has a risk factor for germline (inherited) cancer (e.g., NCCN Guidelines for Prostate Cancer), and • The patient has not been previously tested with the same germline genetic content. 	<p>except with valid TAR override</p>	
<p>0488U Obstetrics (fetal antigen noninvasive prenatal test), cell-free dna sequence analysis for detection of fetal presence or absence of 1 or more of the Rh, C, c, D, E, Duffy (Fya) or Kell (K) antigen in alloimmunized pregnancies, reported as selected antigen(s) detected or not detected</p>	<p>Yes</p>	<p>A TAR requires documentation of the following criteria:</p> <p><u>For fetal RhD antigen status</u></p> <ul style="list-style-type: none"> • The patient is currently pregnant, and • The pregnant patient is RhD negative, and • The pregnant patient has not been tested with another cell-free DNA test for fetal RhD status during the same pregnancy. • The paternal RhD status is either heterozygous or unknown, and • The pregnant member is not alloimmunized to RhD during a shortage of anti-D immune globulin, or the pregnant is alloimmunized to RhD. <p><u>For fetal status of non-RhD red blood cell (RBC) antigens</u></p> <ul style="list-style-type: none"> • The patient is currently pregnant, and • The pregnant patient is alloimmunized to one or more non-RhD RBC antigens, and • The paternal non-RhD RBC antigen status is either heterozygous or unknown, and 	<p>Reimbursement will be limited to once per pregnancy unless there is documentation of medical necessity.</p>	

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		<ul style="list-style-type: none"> The pregnant patient has not been tested with another cell-free DNA test to determine fetal status of non-RhD RBC antigens during the same pregnancy. 		
<p>0493U Transplantation medicine, quantification of donor-derived cell-free DNA (cfDNA) using next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA</p>	Yes	<p>A TAR requires documentation of the following criteria: For kidney transplant recipients</p> <ul style="list-style-type: none"> There is clinical suspicion for acute kidney allograft rejection and the member has not been tested with another donor-derived cell-free DNA test for the same episode, and The test must be ordered by a nephrologist or kidney transplant surgeon, and Member is at least one month post-kidney transplant, and Member is 18 years of age or older, and Member is not pregnant, and Member has not received a kidney transplant from their twin, has not undergone multiple organ transplants, and has not undergone bone marrow transplantation 	N/A	Partnership would consider for heart, lung and liver transplant with MD review for medical necessity.
<p>0494U Red blood cell antigen (fetal RhD gene analysis), next-generation sequencing of circulating cell-free DNA (cfDNA) of blood in pregnant individuals known to be RhD negative, reported as positive or negative</p>	Yes	<p>A TAR is required with documentation of the following criteria: <u>For fetal RhD antigen status</u></p> <ul style="list-style-type: none"> The patient is currently pregnant, and The pregnant patient is RhD negative, and The pregnant patient has not been tested with another cell-free DNA test to determine fetal RhD status during the same pregnancy, and 	Reimbursement will be limited to once per pregnancy, unless there is documentation of medical necessity.	

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		<ul style="list-style-type: none"> The paternal RhD status is either heterozygous or unknown, and The pregnant member is not alloimmunized to RhD during a shortage of anti-D immune globulin, or the pregnant member is alloimmunized to RhD. 		
<p>0523U Oncology (solid tumor), dna, qualitative, nextgeneration sequencing (ngs) of singlenucleotide variants (snv) and insertion/deletions in 22 genes utilizing formalin-fixed paraffin-embedded tissue, reported as presence or absence of mutation(s), location of mutation(s), nucleotide change, and amino acid change</p>	Yes	<p>A TAR requires documentation of the following criteria:</p> <ul style="list-style-type: none"> The member has been diagnosed with either non-small cell lung cancer (NSCLC) or colorectal cancer, and Management is contingent on the test results 	Once in a lifetime	Previously 0448U
<p>0540U Transplantation medicine, quantification of donor-derived cell-free DNA using next generation sequencing analysis of plasma, reported as percentage of donor-derived cell free DNA to determine probability of rejection</p>		<p>A TAR requires documentation of the following criteria:</p> <p>For kidney transplant recipients</p> <ul style="list-style-type: none"> There is clinical suspicion for acute kidney allograft rejection and the member has not been tested with another donor-derived cell-free DNA test for the same episode, and The test must be ordered by a nephrologist or kidney transplant surgeon, and Member is at least one month post-kidney transplant, and Member is 18 years of age or older, and Member is not pregnant, and Member has not received a kidney transplant from their twin, has not undergone multiple 	N/A	Partnership would consider for heart, lung and liver transplant with MD review for medical necessity.

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		organ transplants, and has not undergone bone marrow transplantation.		
<p>0543U Oncology (solid tumor), next-generation sequencing of DNA from formalin-fixed paraffin-embedded (FFPE) tissue of 517 genes, interrogation for single- nucleotide variants, multi-nucleotide variants, insertions and deletions from DNA, fusions in 24 genes and splice variants in 1 gene from RNA, and tumor mutation burden</p>	Yes	<p>A TAR requires documentation of the following criteria: <u>For Somatic Testing</u></p> <ul style="list-style-type: none"> • The member has recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer, and • Either the member has not been previously tested using the same next-generation sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and • The decision for additional cancer treatment is contingent on the test results. <p>Independent of the above criteria, somatic testing may be approved if the test is approved by the U.S. Food and Drug Administration (FDA) as a companion diagnostic device, and the decision for additional treatment is contingent on the test results.</p>	Once in a lifetime	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>0094U Rapid Whole Genome Sequencing (rWGS) Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis</p>	<p>No</p>	<p>Per Assembly Bill (AB) 133 (2021-2022 Regular Session), Rapid Whole Genome Sequencing, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, is a covered benefit for any Medi-Cal beneficiary who is:</p> <ul style="list-style-type: none"> • One year of age or younger AND • Is receiving inpatient hospital services in an intensive care unit. 	<p>Once in a lifetime</p>	<p>This is not an outpatient benefit. Medi-Cal does not cover rapid or ultra-rapid whole genome sequencing in the outpatient setting.</p>